IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	MDL No. 1456 CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris **FILED UNDER SEAL**

EXPERT REPORT OF JANUSZ A. ORDOVER

markups over ASP for Remicade and therefore did not suffer economic harm.

18. Ortho Biotech's pricing and reporting practices with respect to Procrit were consistent with payors' understanding and expectations regarding the relationship between AWP, WAC, and ASP for brand name pharmaceuticals. Accordingly, payors in Classes 1, 2, and 3 did not over-reimburse for Procrit, and therefore did not suffer economic harm.

III. Payors' Awareness of the Relationship between AWP and Physician Acquisition Costs

A. Introduction

19. According to Plaintiffs' expert Dr. Hartman, had Medicare and TPPs possessed better information on the actual spreads that existed between AWP and physician acquisition costs, they would have negotiated lower reimbursement rates for the drugs at issue in this litigation.[7] Based upon my review of the evidence in this case (*see* Exhibit 3), as well as my past experience analyzing the economics of the pharmaceutical industry, the assumption underlying Dr. Hartman's opinion, namely that payors were grossly uninformed about the actual differences between AWP and physicians' acquisition costs (the spreads), is inconsistent with how the markets for branded prescription drugs tend to operate.

B. Payors' Knowledge of Spreads

20. Medicare and TPPs had available to them a plethora of information sources regarding the spreads between AWPs and acquisition costs for physician-administered drugs, and thus understood, or at least could have readily concluded, that AWP did not represent a reliable signal for providers' acquisition costs. Various U.S. government studies that examined

[7] Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calculation of Damages ("Hartman December 2005 Declaration"), December 15, 2005, p. 10.

differences between AWP and physicians' acquisition costs are a readily available and reliable source of such information. These studies found a wide range of spreads between AWP and acquisition costs, and reached the unambiguous conclusion that AWPs did not serve as a reliable proxy for the transactions prices between providers and drug manufacturers. Indeed, the very Medpac study on which Dr. Hartman purportedly relied to formulate his yardstick explicitly refers to studies conducted by several Government agencies that demonstrate that AWP-based Medicare reimbursement methods lead to payments that "far exceed providers' costs."[8]

21. Rather than review or even summarize the evidence along these lines, as it is contained in the reports of Dr. Gaier and Dr. Bell, I will merely cite two illustrative examples. Thus, a 1992 report issued by the Department of Health and Human Services Office of Inspector General (OIG) stated that:

> "Our review of invoices revealed that the 13 chemotherapy drugs [for which spreads were examined] can be purchased at amounts below AWP. This fact indicated that AWP is not a reliable indicator of physician cost; indeed, Red Book officials confirmed that the AWP is not designed to reflect physicians' costs."[9]

For the 13 drugs examined in the study, physician acquisition costs represented a discount from AWP of anywhere from 9% to 83%.[10]

22. Similarly, a 1997 OIG study examined average Medicare allowed amounts and physician acquisition costs in 1995 and 1996 and reached a similar conclusion. The study found that in 1995, the difference between the

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[8] "Variation and Innovation in Medicare," Medpac, June 2003, at p. 150. *See, also, Id.* at p. 153 ("A continuing series of investigations by the OIG ... demonstrated that this [AWP-based] method resulted in Medicare paying far more than other public purchasers for these drugs.") and at p. 155. ("After implementation of the 1997 BBA reform, continued investigations by the OIG (2001), the Department of Justice, and the GAO (2001b) concluded that Medicare still paid for drugs at rates well above providers' acquisition costs.")

[9] "Physicians' Costs for Chemotherapy Drugs," Department of Health and Human Services Office of Inspector General, November 1992 ("OIG 1992"), p. 5.

[10] *Id.* Appendix III.

average Medicare reimbursed amount and average acquisition costs, expressed as a discount from the allowed Medicare amount, ranged from 14% to 90%.[11] Analogous findings for 1996 were 13% to 87%.[12] Responding to the study, the Health Care Financing Administration (HCFA) concluded that:

> "The published AWPs currently used by Medicare carriers to determine reimbursement do not resemble the actual wholesale prices which are available to the physician and supplier communities that bill for these drugs."[13]

23. As I indicated, these studies are only two examples of numerous Government reports that have highlighted the fact that acquisition costs can vary substantially from the published AWP. A more complete discussion of these Government studies can be found in the Declarations of Dr. Gaier and Dr. Bell.[14] My review of these expert reports, as well as a sub-set of the extensive evidence collected by these two experts, leads me to believe that there was during the class period widely and publicly available information regarding the substantial variation in spreads between AWP and physicians' acquisition costs. In light of the availability of such information, it is not credible for Plaintiffs and Dr. Hartman to assert that Medicare and TPPs negotiated reimbursement rates in a fog of imperfect information and under the mistaken assumption that a drug's AWP represented a reliable indicator of providers' acquisition costs.[15] It is my understanding that reimbursement

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[11] "Excessive Medicare Payments for Prescription Drugs," Department of Health and Human Services Office of Inspector General, December 1997 ("OIG 1997"), Appendix B.

[12] *Id.*

[13] *Id.* Appendix D-2.

[14] *See, e.g.*, [Draft] Declaration of Eric M. Gaier, Ph.D., March 22, 2006 ("Gaier Declaration"), at pp. 11-19; Declaration of Greg Bell, March 20, 2005, at pp. 49-57. *See, also*, Expert Report of Fiona Scott Morton Draft ("Morton Report"), March 20, 2005, at p. 9.

[15] It is important to note that for AWP to be a reliable indicator of acquisition costs or ASP it is not necessary that the spread be a constant x% for each and every PAD. Any spread will do for this purpose as long as it is correlated with AWP. Moreover, even if spreads vary across drugs or over time, this does not mean that AWP fails to represent a reliable indicator.

rates were negotiated consistent with the relative leverage of the parties involved, including the relative importance to the TPP of individual physicians and/or physician groups, *i.e.*, the value to the payor of having the physician or group belong to the payor's network of providers.[16]

24. Although some physician or physician groups may have some market power of the type described above, and thus could negotiate more lucrative reimbursement rates with TPPs and lower acquisition costs with drug manufacturers, rivalry among physicians to attract more patients to their practices would tend to compete away the margins that these physicians could earn over a long haul to the point where they would just reflect normal returns to the physicians' practices. Insofar as some physicians may earn slightly greater margins on their practices than other physicians is not necessarily a reflection of these physicians' market power. Rather, superior margins earned by some physicians are a reflection of the above-average practices that these physicians have and thus comprise a market-driven reward for these exceptional physicians.[17]

25. On a number of occasions during the putative damages period, HCFA and the federal government have considered and proposed modifications to Medicare's reimbursement policies, including the adoption of reimbursement mechanisms not based upon AWP. These various proposals clearly demonstrate public awareness of the fact that AWPs were not generally a tight signal for provider acquisition costs, as well as the availability of alternative, non-AWP based reimbursement mechanisms.[18]

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[16] Indeed, Dr. Rosenthal acknowledged in her deposition that certain physician or clinic groups may have market power in negotiating with TPPs (*See* Deposition of Meredith Rosenthal, Ph.D. ("Rosenthal Deposition"), February 22-23, 2006, at pp. 250-251, 308-309, 311, 312-313, 319-320, 492-512).

[17] Dr. Hartman apparently agrees that certain physicians, in particular specialists like oncologists and urologists, will possess relatively greater leverage in their negotiations with payors, as well as with drug companies. (*See* Deposition of Raymond S. Hartman, Ph.D. ("Hartman Deposition"), February 27-March 1, 2006, at pp. 860-862.)

[18] For a more detailed discussion of these various proposals, see Gaier Declaration at pp. 19-21.

Thus, there is no merit to Dr. Hartman's implicit assertion that Medicare until recently clung to an AWP-based reimbursement methodology because it did not understand that AWP did not necessarily predictably correlate with physicians' acquisition costs.

26. In terms of pricing information available to TPPs, several sources bear mentioning. First, TPPs often purchase significant volumes of physician-administered drugs directly from manufacturers and wholesalers.[19] As noted by Dr. Gaier in his Declaration, the prices paid by TPPs for these therapies were generally equal to, and in some cases even lower than, the average selling prices calculated by Dr. Hartman.[20] It makes no sense to argue, as does Dr. Hartman, that TPPs who are direct purchasers of the physician-administered drugs at-issue in this litigation would have paid excessive mark-ups over the ASP for these same drugs when reimbursing physicians due to incomplete knowledge or lack of understanding that AWP is not a tight predictor of ASP. These TPPs had clear knowledge that PADs were often available to healthcare providers at differing and at times quite large discounts from AWP.

27. Dr. Hartman's argument regarding the functioning of the marketplace seems to be that while TPPs may have had some knowledge regarding the actual spreads, or the fact that spreads differed across PADs, the extent of this knowledge was not sufficient to protect them from the putative fraudulent scheme. Dr. Hartman arrives at this conclusion simply by observing that actual spreads on the drugs at issue in this litigation exceeded his 30% threshold for determining liability.[21] That is, Dr. Hartman claims

[19] *See, e.g.*, Gaier Declaration at p. 40; Morton Report at p. 7.

[20] *See* Gaier Declaration at p. 40. Note that the ASP, as referred to and calculated by Dr. Hartman, is a measure that estimates the drug acquisition costs to healthcare providers.

[21] *See* Hartman Deposition at pp. 1018-022. Or stated more in line with Dr. Hartman's preferred terminology, TPPs, through their revealed preferences, *i.e.*, their chosen actions, demonstrated their lack of significant awareness of the spreads between AWP and acquisition costs. As I indicate in the text, Dr. Hartman's analysis does nothing more than assume the result.

that any spread in excess of 30% is conclusive evidence that TPPs *did not* have sufficient knowledge or information to protect themselves against fraudulent manipulation of the spreads. But this argument only shows that Dr. Hartman is simply assuming his conclusion: Dr. Hartman's reasoning does not offer any independent economic analysis that would disprove that TPPs negotiated reimbursement rates with at least a substantial awareness and understanding of physicians' acquisition costs and their relationship to AWPs. That is, he simply assumes without providing proper economic support that spreads in excess of 30% cannot reasonably arise in a marketplace in which TPPs have adequate access to pertinent information *or* in a marketplace in which information may be imperfect but in which competitive forces tend to constrain the overall returns that physicians who administer PADs earn on their practices. Nor does Dr. Hartman provide any economic basis for the fact that the spreads for some PADs were below 30% throughout the relevant period. His yardstick methodology and, therefore, the proffered reasoning, would appear to assume that pricing information for these drugs was sufficiently transparent to render the alleged manipulation infeasible, but he offers no justification whatsoever for how the transparency of pricing information varies markedly across PADs.

28. Second, TPPs own employees were also a potential source of information regarding discounting practices. In particular, employees who had past exposure to information relating to providers' acquisition costs, as hospital administrators, practicing physicians or pharmacists, or as employees of drug manufacturers or wholesalers were in a position to convey this information to those who decided on reimbursement policies.[22] Where such individuals brought their prior experiences to a TPP, the TPP could be expected to at least try to use that knowledge to improve its assessment of

[22] *See* Gaier Declaration at pp. 49-52.

the differences between acquisition costs and AWPs and to more effectively negotiate reimbursement terms with physicians or physician groups.[23]

29. Of course I am not arguing, or even suggesting, that information on transaction spreads is perfect, ubiquitous, or disseminated immediately. However, the available evidence makes clear that there are many sources of qualitative and quantitative information regarding these spreads, which leads me to reasonably conclude that Medicare and TPPs alike were not (and should not have been) operating under the mistaken premise that AWP invariably represents a reliable predictor of acquisition costs.[24] Thus, as I explain in greater detail in the next section, in their negotiations with physicians, Medicare and TPPs would have – or should have – used whatever knowledge they had to control the margins between the reimbursed amounts and physicians' acquisition costs, taking into account the constraint that physicians require a certain margin on PADs (and other services) in order to earn an acceptable rate of return on their practices.

C. Pharmaceutical Industry Economics

30. Dr. Hartman's analysis of permissible spreads (or spreads that would arise in his but-for world) is also marred by his implausibly constricted view of what constitutes a permissible differential or spread between AWP (which I assume *arguendo* is the reimbursed amount) and acquisition costs. He takes the position that any differential above his promulgated threshold evidences fraudulent behavior and a lack of information by the payors and thus concludes that any differential in excess of 30% must stem from unlawful conduct aimed at defrauding payors. Similarly, Dr. Rosenthal interprets Dr. Hartman's "yardstick" as indicating that any amount of spread above 30%

[23] *See Id.* and the Appendix for examples of TPPs that employ individuals with experience in the provider community.

[24] In this context it is important to point out that from the perspective of the payor it is not important whether AWP is equal to AC but, rather whether there is a reasonably predictable relationship between AWP and the acquisition cost for a given drug or category of drugs.

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DECLARATION OF JOHN P. GOULD

MARCH 22, 2006

17. Thus, Plaintiffs have no economic basis to support their claims that payers were deceived.

A. PUBLICLY AVAILABLE PRICE DATA

18. There were several sources of publicly available data on the price at which actual sales of Zoladex occurred throughout the class period.

19. First, IMS Health reported data on transactions prices for various trade classes.[6] These data are publicly available for purchase. I understand that purchases by doctors are classified by IMS as the "Clinic" trade class.[7] As shown in Figure 2, IMS data clearly show AstraZeneca's volume price discounting to physicians. The average prices reported by IMS clearly show the trends in the ASP that Dr. Hartman calculated, increasing slightly between 1990 and 1997 and then falling substantially by 1998 before leveling out. For example, IMS reported an average price for the clinic trade class of less than $220 from 1999-2005, a period during which AWP was $470. Thus, publicly available information reflected the

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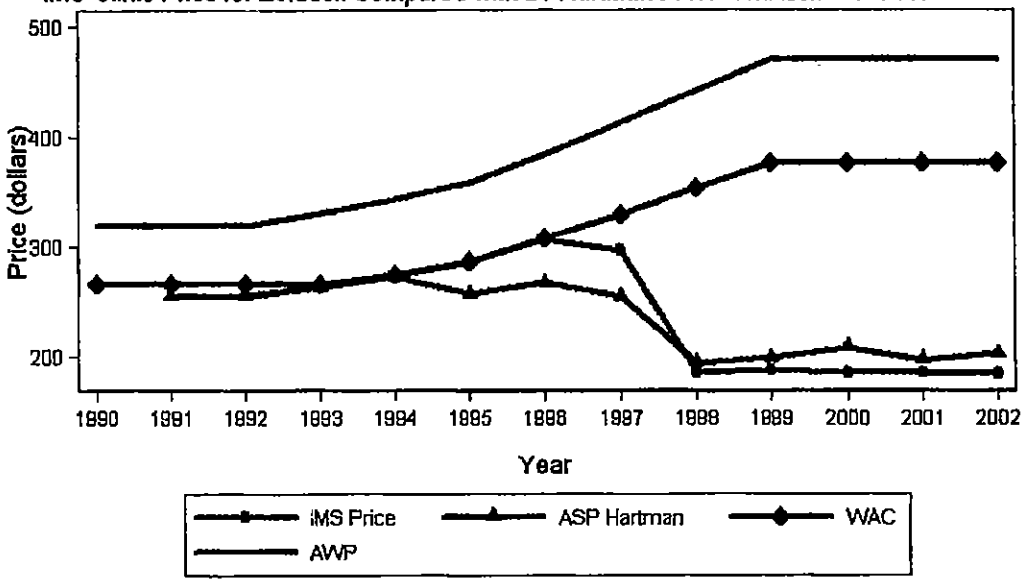
[6] According to its website and 2004 Annual Report, IMS is the leading provider of business intelligence and strategic consulting services for the pharmaceutical and healthcare industries in the world. The company was founded in 1954 and now operates in more than 100 countries worldwide IMS monitors 75 percent of drug sales in those 100+ countries and 90 percent of all US sales. IMS collects its data from 29,000 data suppliers at 225,000 supplier sites worldwide tracking more than 1 million products from more than 3,000 drug manufacturers. The company's customers include virtually every major pharmaceutical manufacturer and biotechnology firm, as well as professional service firms, financial analysts, government and regulatory agencies, researchers and educators. IMS's 2004 revenues exceeded $1.8 billion.

[7] These data come from IMS's NSP database. As described by IMS: "Information in **IMS National Sales Perspectives**™ is derived from IMS Health's DDD service, and is the most comprehensive, national-level prescription sales database. The National Sales Perspectives tracks sales activity for all pharmaceutical distribution channels, including major retail food stores and chains, mass merchandisers, independent pharmacies, mail service pharmacies, hospitals, clinics, closed-wall HMOs, long-term care, home health care, and prisons/universities. Sales information is compiled from more than 100 pharmaceutical manufacturers and more than 300 wholesaler and chain warehouses." (http://www.imshealth.com/ims/portal/front/indexC/0,2773,6599_77075636_0,00.html)

differences between AWP and the price at which providers acquired Zoladex from AstraZeneca.

Figure 2
IMS Clinic Price for Zoladex Compared with Dr Hartman's ASP and Zoladex WAC and AWP



Note: Classes 3, 5 and 6 represent Government and Hospitals and are excluded.
Source: First Data Bank, Dr. Hartman's 2/23/06 Addendum and IMS NSP.

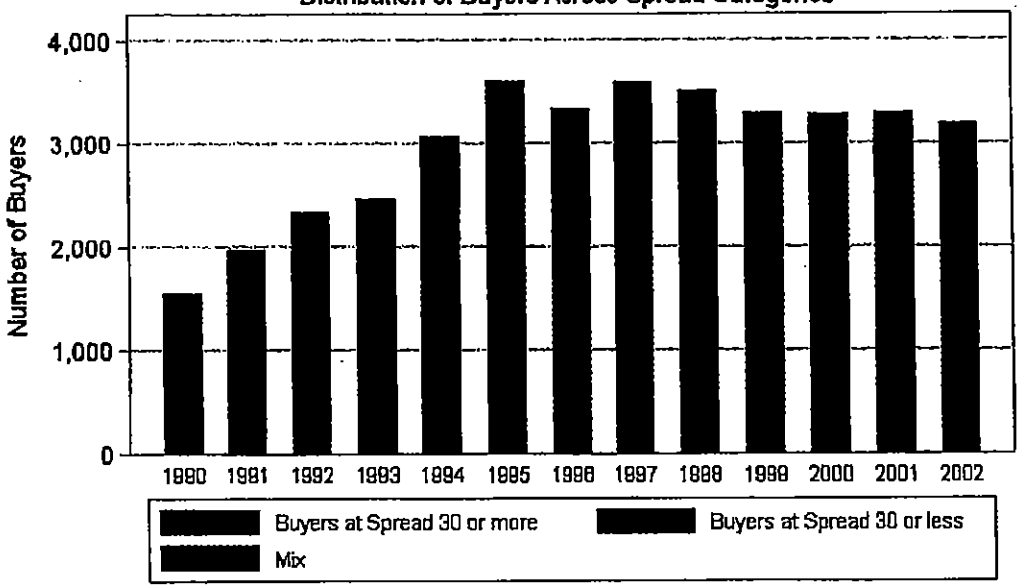
20. Second, some TPPs, including TPPs in Massachusetts, directly negotiated with AstraZeneca a discount from WAC for Zoladex greater than 3.84 percent or, equivalently, they negotiated more than the 30 percent spread (in Dr. Hartman's terminology) between AWP and ASP that Dr. Hartman claims is the maximum legal amount.[8] These include the Massachusetts TPPs Harvard Community Health Plan, Med Partners, Vanguard Medical Associates, and Fallon Community Health Plan. By 1999, discounts of 50 percent of WAC (or spreads of 150 percent) were common for Massachusetts TPPs. Clearly, these firms knew that

[8] Dr. Hartman, Dr. Rosenthal and the Plaintiffs mischaracterize how manufacturers behave by focusing on the "spread" between ASP and AWP, or on the amount by which AWP "exceeds" ASP. In fact, actual provider acquisition costs result from discounting by AstraZeneca and other manufacturers from WAC – the list price. AWP (and thus the "spread") is not established, as Plaintiffs misleadingly imply, by raising AWP above predetermined acquisition costs or ASP.

AWP was not a transactions price and that volume discounts on Zoladex were available to certain purchasers. Thus, the very payers that Plaintiffs claim have been injured because they were deceived were benefiting from the discounts that Zoladex made available to certain direct customers.

21. Third, the large number of urologists and other customers who bought Zoladex at prices below AWP means that knowledge of actual pricing was widespread. Figure 3 shows that there were thousands of direct buyers of Zoladex each year. The figure also shows that a large fraction of these buyers purchased Zoladex at a spread greater than 30 percent during the years in which Dr. Hartman concludes that the average spread was fraudulent. The number of customers with knowledge of actual transactions price is too large for concealment to be realistic. Moreover, the volume discounts offered by AstraZeneca and earned by many urologists were described in the standard incentive contract available to urologists and urology groups. These discounts were not negotiated with providers individually and secretly, as Plaintiffs appear to claim, but rather were explicitly described in a standard contract form shared with thousands of entities.

Figure 3
Distribution of Buyers Across Spread Categories



Note: Classes 3, 5 and 8 represent Government and Hospitals and are excluded.
Source: AZ Zoladex Sales (AZ0582114)

22. Fourth, government studies show public awareness of the discounts available on Zoladex. For example, an OIG report published in November 1998 discussed the price at which the Veterans Administration purchased Zoladex, and noted how much Medicare could save by obtaining the same price. The report noted that the median VA price in 1998 was $206.29, while the median HCFA (Medicare) price was $389.98, or about 90 percent higher. OIG noted that Medicare and its beneficiaries could have saved about $60 million in 1998 if allowed amounts for Zoladex equaled prices obtained by the VA. OIG concluded that "This report provides **additional** evidence that published AWPs used in determining the Medicare allowed amounts for certain prescription drugs can be many times

greater than actual acquisition costs available in the marketplace."[9] (Emphasis added.)

23. The version of the 1998 OIG report made available to the public included a letter of acknowledgement from the Administrator of HCFA, Nancy-Ann Min DeParle, in which she expressed her views on the report's recommendation as follows:

> We [HCFA] concur [with the OIG recommendation to use authorities in the Balanced Budget Act of 1997 to reduce Medicare's unreasonably high payments for certain drugs]. In the President's FY 1998 budget, the Administration proposed a change in the law to reduce Medicare's high payments for certain drugs. Under this proposal, physicians and suppliers who bill Medicare for outpatient drugs . . . would be paid their acquisition cost. This would have removed the mark-up currently being paid above the true market price. While Congress did not enact our recommendation, the Balanced Budget Act of 1997 provided for program payment at the lower of the submitted charge of 95 percent or the average wholesale price. The President indicated in his radio message of December 13, 1997, that the Congress did not go far enough in the BBA, so we again submitted this proposal in the President's FY 1999 budget.[10]

Rather than being deceived, as Plaintiffs claim, this response makes clear that HCFA and others in the government were fully aware of discounts from AWP available in the marketplace.

24. Fifth, in 2001, Congress began to consider changing how Medicare reimbursed providers for Part B drugs, based in part on a study it had commissioned from the Government Accountability Office ("GAO") in 2000 and other (publicly available) studies of drug pricing from the Office of Inspector General ("OIG") and GAO. In 2003, the Medicare Modernization Act became law, which changed the reimbursement method. The public deliberations over changing Medicare

[9] OIG, "Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs," (OEI-03-97-00293) (November 1998).
[10] Ibid, p. C-2 and C-3.

reimbursement policy added to the knowledge that AWP was not an average transactions price.

25. Finally, this lawsuit was filed in 2002, adding to the already considerable knowledge of the significance of AWP.

26. Thus, throughout the class period a variety of systematic and unsystematic data and information was publicly available about how AWP was determined (as a markup over a list price, or WAC) and the fact that AWP was not based on actual provider acquisition costs. Information also was widely available that actual transactions for Zoladex and other Part B drugs frequently occurred at prices below AWP.

B. ECONOMICS OF INFORMATION

27. A flawed presumption that runs throughout Plaintiffs' claims and through the Declarations submitted by their experts is that third-party payers accept AWP passively as a signal for acquisition prices, without questioning whether this is simply a list price. Plaintiffs' expert Dr. Hartman claims that TPPs have no incentive to seek out information about actual transactions prices, because the amount they expect to save may be only a small fraction of their total spending on health care. According to Dr. Hartman, the **"unimportance [of pharmaceutical expenditures to payers] is even more important for physician-administered drugs**, which represent a small portion of an already small component of costs (i.e., the cost of all pharmaceuticals)."[11] (Emphasis in original) Plaintiffs' experts

[11] Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calculation of Damages, December 15, 2005, ¶

have cited economist Alfred Marshall (Principles of Economics, 1890) as support for this claim, because he asserted that the demand for a good may be less price elastic when expenditure on the good accounts for only a small part of the total budget of the consumer. This, however, is an incorrect application of economic theory to the facts of this case, because the gains to a payer, or to payers as a group, from obtaining information that could result in lower reimbursement rates can be very large relative to the cost of acquiring the information when the total volume of purchases affected by the price reduction that could result is large.

28. The idea that the incentive to gather information on purchases is affected by the cost of getting that information compared to the expected benefit from having that information was explored in depth by Professor George Stigler of the University of Chicago. Stigler won the Nobel Prize in economics in 1982 and the Nobel committee recognized the importance of his contribution to understanding the "market" for information in granting the prize. In the language of the Nobel Committee:

> According to traditional theory, the result of optimization and market processes should be that every commodity, except for transport costs, is sold for one and the same price everywhere. But, in practice, price variation is observed on most markets. Stigler has shown that this can be explained if the costs of searching for, and diffusing information about, goods and prices are incorporated in the model along with production and transport costs. The basic properties of traditional theory do not have to be challenged. It has merely been too schematic by assuming "perfect information", in the same way that fundamental theories in physics simplistically assume the existence of a vacuum.
>
> A market participant's lack of knowledge about goods and prices can, of course, be alleviated by collecting and furnishing information. **The amount of information a firm or household acquires is guided by the same comparisons between costs and benefits as the production of any**

> **commodity. That is, information is gathered until the expected utility of further search no longer outweighs additional search costs. The information a subject acquires is consciously chosen. Conversely - and more provocatively - even a lack of market information is rationally and deliberately chosen.**[12]
>
> (Source: Press release from the Royal Swedish Academy of Sciences. October 20. 1982. See http://nobelprize.org/economics/laureates/1982/press.html. Emphasis added.)

29. Because, under Dr. Harman's assumptions, the potential gain to TPPs from a lower reimbursement amount can be very large, application of these economic principles shows that TPPs have a substantial incentive to obtain information on actual transactions prices if doing so would save them money, particularly for a drug like Zoladex that was widely prescribed. As I noted above, the number of providers and other parties with such information is huge – there are over 10,000 current urologists alone[13] – and AstraZeneca's offer of specific tiers of volume discounts was provided in a standard incentive contract offered to urologists.

30. The fact that AWP frequently differed from the actual transactions prices was not the secret that the Plaintiffs suggest, but was widely known by participants in the health care industry. For example, in testimony in 2001 on Medicare payment for drugs before the House Energy and Commerce Subcommittees on Oversight and Investigations and Health, Thomas A. Scully, who was then Administrator, Centers for Medicare & Medicaid Services U.S. Department of Health and Human Services, stated,

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[12] Stigler develops the foundational ideas in his article "The Economics of Information", *Journal of Political Economy*, June 1961.

[13] 2005 ABMS Annual Report & Reference Handbook, p. 86, and Physical Characteristics and Distribution in the US, 2005 edition, p. 24.

This Committee, CMS, the Department's Office of the Inspector General (IG), and others have long recognized the shortcomings of AWP as a way for Medicare to reimburse for drugs. The IG has published numerous reports showing that true market prices for the top drugs billed to the Medicare program by physicians, independent dialysis facilities, and durable medical equipment suppliers were actually significantly less than the AWP reported in the Red Book and like publications.

He noted further that,

In May 2000, the DOJ and the National Association of Medicaid Fraud Control Units made accurate market wholesale prices for 49 drugs covered by Medicaid available to State Medicaid programs and to First Data Bank, a drug price compendia owned by the Hearst Corporation. These wholesale prices, culled from wholesale catalogs circulated among the provider community, reflected the actual Average Wholesale Prices for these drugs far more accurately than the drug manufacturers' AWP. Last year, HCFA sent this new information to Medicare carriers and instructed them to consider these alternative wholesale prices as another source of AWP data in determining their January 1, 2001 quarterly update for many of these drugs. However, due to concerns about Medicare payments related to the administration of the chemotherapy and clotting factor drugs, the Administration instructed our carriers not to use the data for those drugs at that time. (Source Scully, ibid.)

31. This testimony shows that throughout the class period there has been a substantial incentive to get information about actual pharmaceutical prices if, by doing so, TPPs could save money. Parties with an interest in understanding pharmaceutical pricing acquired that information. Clearly, knowledge that transaction prices differed from AWP has been widely available in the health care industry for some time. As Scully's testimony shows, the failure of the government to act on information that AWP and transactions prices differed was an explicit decision; the failure of other parties with access to the same information cited by Scully and with access to the other information I described above likewise demonstrates that they preferred the status quo.

V. PLAINTIFFS MISCHARACTERIZE THE PURPOSE OF WAC

32. Plaintiffs claim that AWP – a published price – should reflect formulaically the average price at which actual transactions occur. They claim further that AWP in fact was not properly related to transactions prices, and that the two diverged in a way that was fraudulent and injured payers.

33. Plaintiffs mischaracterize AWP, which is formulaically related to WAC, and the role of WAC in determining the structure of prices in the drug industry. Like any "list" price, WAC caps the distribution of prices charged to different buyers, and it represents the price from which AstraZeneca then discounts to some customers in order to increase its sales and profits. Data show that throughout the class period AstraZeneca made sales at WAC to some customers, while other customers obtained various levels of discounts.[14]

34. Thus, there was no economic foundation for the Plaintiffs' claim of fraud because the Zoladex WAC, which is formulaically related to AWP in a simple and stable relationship, is precisely what a published "list" price in this and virtually any other industry represents. It is the price charged to those customers unable to obtain discounts because they do not satisfy the manufacturer's requirements (such as buying in sufficient quantity to obtain a volume discount) or because they fail to bargain, or they bargain ineffectively, to obtain price concessions from the supplier. Despite the substantial number of providers that qualified for discounts on Zoladex, others throughout the Class Period did not, making it in

[14] For the period 1995-2002, AstraZeneca's direct sales at WAC to customers other than wholesalers, totaled $23.6 million.

AstraZeneca's interest to keep the list price that those customers paid above the discounted price charged to other buyers.

VI. PLAINTIFFS CLAIM THAT REDUCTIONS IN TRANSACTIONS PRICES WITH AWP UNCHANGED ARE FRAUDULENT, A POSITION THAT MAKES CLEAR THEY ARE COMPLAINING ABOUT PRICE DISCOUNTING AND THE EFFECTS OF COMPETITION

35. In their Complaint, Plaintiffs contend that AWPs were inflated. In his Declaration, Dr. Hartman offers the following formulation of the allegations, namely that "the alleged AWP scheme was effectuated when a manufacturer increased the AWP of the drug and/**or decreased its ASP in order to offer financial incentives to providers to move market share.**"[15] (emphasis added)

36. This way of characterizing the alleged "fraud" makes clear that the Plaintiffs are complaining about how the parties that control usage of a manufacturer's product (typically the providers who prescribe and administer Part B drugs) use competition to force manufacturers to reduce their prices. Even during periods when WAC was unchanged for years, Dr. Hartman finds fraud and damage if AstraZeneca increases the discounts it gives to some of its customers. Thus, Dr. Hartman claims there is fraud when competition causes transactions prices to decline, even if the list price remains unchanged. Using his methodology, Dr. Hartman would also find fraud whenever an increased number of urology practices chose to take advantage of existing volume discounts offered by AstraZeneca.

[15] Hartman Declaration, ¶ 58, p. 38.

37. An example from the publishing industry can help illustrate why this claim has no merit and its economic logic is to make competitive price responses illegal. Magazines typically have cover prices that are paid by customers who buy a single issue off the newsstand. Magazines also typically have a published "list" price for a subscription, often related to the price that would be paid to purchase a certain number of single issues. Yet, subscribers to popular magazines frequently pay rates far lower than those reflected in the cover price or the published subscription price. Discounts may be extremely large. For popular magazines like Newsweek and Time, subscription offers for more than 50 percent off the cover price or the list subscription price (even 70 or 80 percent) are common. This discounting occurs because publishers compete for subscribers, using targeted differential and large discounts to attract customers. A reader who obtains an offer of a subscription at "80 percent off the newsstand price" does not know whether other readers are receiving the same offer and, if they received different offers or pay cover price, what the average transactions price at which subscriptions are sold.

38. The same phenomenon occurs in the pharmaceutical industry driven by the competition among products in a therapeutic category and the ability of the buyers that choose among those alternatives to affect a manufacturer's sales and share. As noted in the Third Amended Complaint, "AstraZeneca's documents reveal an intense competition with TAP Pharmaceuticals and its drug Lupron."[16]

39. The anticompetitive implications of the Plaintiffs' fraud allegation, and the incongruous implications of their damage claims, are seen from the Zoladex

[16] See, Third Amended Master Consolidated Class Action Complaint, p. 82.

experience between 2000 and 2001. During those years, WAC (and AWP) were constant (as they have been since 1998). However, between 2000 and 2001, ASP (as calculated by Dr. Rosenthal and Dr. Hartman) declined slightly, thus increasing the spread. According to the Plaintiffs, this decline in ASP would increase damages per unit of Zoladex sold, even though AWP was unchanged. In fact, even if AWP had remained unchanged between 1991 and 1998 at $331.50, the Plaintiffs and their experts still would find AstraZeneca had caused injury and would owe damages. Without any change in AWP between 1991 and 1998, the decline in ASP from $255 in 1991 to $188 in 1998, or by 26 percent, would have resulted in an increase in spread from 30 percent in 1991 to 76 percent in 1998 solely because of increased discounting by AstraZeneca to its customers. Thus, even if there were no "inflation" or change in AWP, competitive pressures would have resulted in an increase in "spread," a development that Plaintiffs would call fraud despite no change in AWP. Any attempt to prevent such price discounting in order to maintain a low spread would inhibit competition.

40. Plaintiffs may claim that AstraZeneca should have lowered WAC (and thus AWP) whenever it decided to increase discounts to its customers. However, there is no historical evidence in the pharmaceutical industry that firms reduce published prices, even as competition increases.[17] Moreover, if a rule that list price had to decline whenever discounting increased were applied generally to pharmaceuticals and other industries, such a rule would have deleterious effects

[17] See, for example, U.S. Congressional Budget Office, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry, July 1998 (www.cbo.gov/showdoc.cfm?index=655&sequence=1 (downloaded 2/28/06), which says that "[v]arious studies have found that generic entry has little effect on the prices of brand-name drugs, which continue to increase faster than inflation."

on the functioning of competitive markets for several reasons. First, it could deter sellers from offering selective discounts (often a major factor in the functioning of competitive markets), because any discount offered to one customer could then "spill over" to other customer groups, where the seller would stand to lose more revenue than it gained in the market where it wanted to discount. Second, it could limit a seller's scope for negotiations with different customer groups. Third, it could make it more difficult or costly to raise prices at a later time, when costs or competitive conditions have changed.

41. Thus, there are valid strategic and business reasons why firms do not want to reduce WAC for existing products. These reasons have nothing to do with the claims of fraud advanced by Plaintiffs.

42. The Plaintiffs' experts' description of the but-for world fixes the spread between ASP and AWP at no greater than 30 percent of ASP. Equivalently, in this but-for world, AstraZeneca would be liable for damages if it offered customers discounts from WAC greater than 3.84 percent. The absurdity of this blatantly anticompetitive restriction is clear when contemplating how this restriction would be applied to other industries.

VII. PLAINTIFFS FAIL TO CONSIDER CHANGES IN THE BUT-FOR WORLD IF SPREADS HAD BEEN CONSTRAINED

43. In their analysis, Plaintiffs focus solely on the spread between AWP and the ASP that their economist calculates, holding constant everything else. This unrealistic approach introduces a substantial error into Plaintiffs' analysis of impact and damages. In particular, Professor Hartman calculates damages assuming that (a)

total sales of each drug would be the same in the but-for world; (b) ASP (and, presumably, the price at which each individual customer purchased) would be the same in the but-for world and (c) reimbursement arrangements of Medicare, TPPs and patients would be the same in the but-for world. Thus, Plaintiffs and Professor Hartman calculate damages by assuming that the only difference between the actual and but-for worlds is that AWP would be lower in this but-for world by an amount required to make the "but-for" spread equal to the percentage that Dr. Hartman claims is appropriate.

44. As I now explain, for several reasons, the assumption that all else remains constant in the but-for world is inconsistent with both economic theory and empirical evidence regarding the market for Zoladex.

A. IN THE BUT-FOR WORLD THERE WOULD HAVE BEEN MORE SALES OF LUPRON, A HIGHER PRICED PRODUCT

45. The history of competition in supply of LHRH agonists that I presented above shows that when it was launched Zoladex faced competition from Lupron, another LHRH agonist. Throughout the class period, as shown in Figure 1, Zoladex had a lower WAC and AWP than did Lupron.[18] If Zoladex sales were lower in the but-for world than in the actual world, more sales would have occurred at higher prices to the extent that providers administered Lupron rather than Zoladex. For patients who, in the but-for world, were administered Lupron instead of Zoladex, co-payments would have been higher (20 percent of a higher AWP), increasing (not lowering) the amount paid by the Class members responsible for those

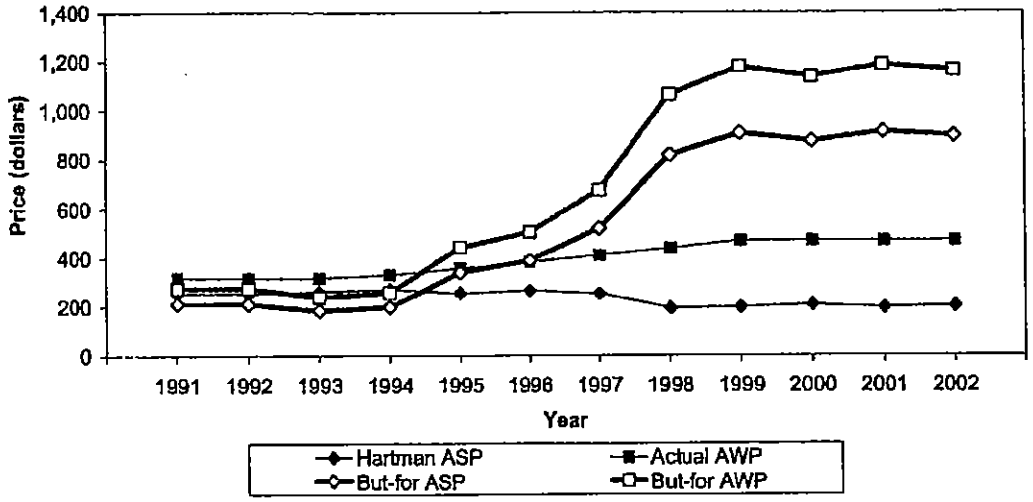
[18] In the discussion that follows I assume that Lupron's conduct – pricing and other marketing – remains unchanged from the historical experience.

copays. As I noted in paragraph 14, in 2003, the Medicare Reimbursement Amount for Lupron exceeded that for Zoladex by $165 per one-month dose, or by 37 percent. Class members' copay amounts would have been higher by the same percentage.

B. ASTRAZENECA AND OTHER FIRMS WOULD HAVE AN INCENTIVE TO REDUCE DISCOUNTS AND RAISE ACQUISITION PRICES TO ACHIEVE A GIVEN PERCENTAGE SPREAD

46. Dr. Hartman claims that any spread greater than 30 percent is fraudulent, because payers expected (and therefore bargained as if) that were the actual provider spread. Assume that the actual spread had been limited to 30 percent (i.e., to a 3.84 percent discount from WAC). A manufacturer like AstraZeneca could satisfy this standard and yet still give providers the same dollar spread by reducing discounts and raising both acquisition prices and WAC. In 1998, for example, the average dollar spread (based on Dr. Hartman's measure of Zoladex ASP) was $223.57, while the percentage spread was 119 percent (given AWP of $411.57). (See Figure 4.) If, instead, AstraZeneca's ASP for Zoladex had been $745.24 and it had set a WAC of $775 (resulting in AWP of $969), then the percentage spread would have satisfied Dr. Hartman's claimed maximum of 30 percent (($969-$745.24)/$745.24=30 percent and $969-$745=$224). According to Dr. Hartman's logic, there would have been no fraud in this case. With this pricing, AstraZeneca still would be giving providers the same dollar incentive to prescribe Zoladex as they have today.

Figure 4
Comparison of Hartman But-For World and Alternative But-For World for Zoladex
(NDC 310096036, 3.6 mg)



Source: Hartman's 2/3/2006 Addendum.

47. In this "non-fraudulent" world, the parties who would be worse off would be payers (Class members) – the parties that Dr. Hartman claims he is trying to protect from fraud. The hypothetical but-for world of higher WAC and higher acquisition prices and the same dollar and percentage spreads generates no damages according to Dr. Hartman. Yet, clearly it is much worse for payers (Medicare, TPPs and individuals) than is the actual world. Thus, if the spread were limited by fiat, economic theory suggests that the result would be higher AWPs, less discounting and higher acquisition prices, so that manufacturers could continue to give providers competitive incentives to prescribe their drugs.

48. It is clear from this analysis that Dr. Hartman does not consider or address the complexities of the "but-for" world.[19] Rather, he makes a number of (tacit)

[19] In his deposition, Dr. Hartman confirms that he has not considered these critical issues:
"Q: But the providers' market power is a constant, right? It will remain the same irrespective of the reimbursement formula that is used?
A: I haven't – I haven't done an analysis. I can't render an opinion on that." (Feb. 27, 2006, p. 864.)

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	

MERITS REPORT AND DECLARATION OF FIONA SCOTT MORTON, PH.D.

March 22, 2006

108. In this section, I discuss several independent reasons why payors were not deceived by large spreads. If even one of these reasons holds, then there was either no fraud or payors could have easily avoided being deceived.

A. Payors had access to plentiful information on prices and spreads

109. One of the cornerstones of Plaintiffs' theory is that payors were unaware of the size of the spreads between AWP and providers' acquisition cost. As noted above,[157] there were numerous government reports and investigations throughout the class period that gave Medicare and private payors indications of the range of discounts on PAD prices in relation to WAC or AWP, for both generic and branded drugs. Dr. Hartman acknowledges that payors made use of such publicly available reports[158] and conducted their own studies;[159] this has been confirmed by Dr. Rosenthal,[160] individual private payors,[161] and Medicare.[162] Dr. Hartman describes some of these sources as informing "market expectations" of "spreads," however these reports provide examples of discounts (from which Dr. Hartman calculated "spreads") substantially larger and more variable than Dr. Hartman's "liability threshold." Note that Dr. Hartman misrepresents what is reported in the government reports: most of the reports present discounts off AWP or WAC—which by definition cannot exceed 100 percent—while Dr. Hartman uses the same discounts to calculate "spreads" (or mark-ups), which are sometimes hundreds or thousands of a percent above costs.

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[157] See section III.A.6.

[158] Hartman Declaration of Dec. 16, 2004, ¶ 51. See, also, Hartman Declaration of Sept. 3, 2004, Attachment D: ¶ 24: "It is reasonable to expect that the findings of these reports form some part of the basis for beliefs about the typical "spread" between AWP and actual acquisition costs of providers (physicians) and retail drug stores."

[159] Hartman Declaration of Dec. 16, 2004, ¶ 15(f), fn. 13.

[160] Rosenthal Deposition, pp. 46–47.

[161] See, for example, Beaderstadt Deposition, pp. 15–16, 19–21; Letter from Nancy-Ann DeParle to members of Congress, in 2000 NHIC Part B Newsletter, pp. 17–18.

[162] "We have followed closely the investigations of drug pricing conducted by the DOJ and the Department of Health and Human Services' Inspector General." See DeParle Letter to Carriers, 2000, at AWP041-0945.

110. Nonetheless, examples of such "spreads" calculated from the discounts in government reports include: albuterol sulfate, 116 percent to 180 percent;[163] doxorubicin, 127 percent to 143 percent;[164] doxorubicin HCL, 215 percent to 224 percent;[165] etoposide, 71 percent to 94 percent;[166] and Zofran, 30 percent to 42 percent.[167] Government officials involved with the Medicare program were informed of large "spreads" and so-called "mega-spreads" before and during the Class period. In 1996 HCFA was informed by Ven-A-Care that "Medicare's reimbursement was excessive and in many cases provided profit margins of more than 500% and, in some instances, more than 1000%."[168] Ven-A-Care stated that"[f]or approximately seven years, we have diligently worked in an attempt to inform responsible government officials, including HCFA and others, of the cause and effect that excessive reimbursements for infusion and inhalation drugs are having on our health care delivery system."[169] Also, the Secretary of the Department of Health and Human Services, Donna Shalala, acknowledged in 1999 the 13-year history of OIG reports documenting "spreads."[170] She also described

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[163] 1997 OIG Report, Appendix B. pp. B-2, B-3 (J7620). "Spreads" were calculated as ("Actual Medicare Allowed Amount" – "Actual Average Wholesale Price") / "Actual Average Wholesale Price". The prices in Appendix B are from 1995–1996, a period when Medicare statutes specified reimbursement at the lesser of AWP and EAC (although the EAC provision was never implemented, as I discuss above).

[164] 1992 OIG Report, pp. 2, 5–6, and Appendix III. "Spreads" were calculated as: (1) for page 5, ("AWP" – "Physician Cost") / "Physician Cost"; (2) for Appendix III, "Invoice Costs Expressed as a Percentage Below the AWP" / (1 – "Invoice Costs Expressed as a Percentage Below the AWP").

[165] 1997 OIG Report, Appendix B. pp. B-2, B-3 (J9000, J9010).

[166] 1997 OIG Report, Appendix B. pp. B-2, B-3 (J9181, J9182).

[167] 1997 OIG Report, Appendix B. pp. B-2, B-3 (J2405 – Ondansetron Hydrochloride).

[168] See, for example, the Letter from Zachary Bentley to Dr. Bruce Vladeck, Administrator, Health Care Financing Administration, regarding Excessive Reimbursements for Certain Pharmaceuticals by the Medicare and Medicaid Programs, October 2, 1996, HHC003-0479–84 ("1996 Bentley Letter to HCFA"), at HHC003-0481.

[169] 1996 Bentley Letter to HCFA, HHC003-0480.

[170] "For the past 13 years, the Office of Inspector General (OIG) has issued a series of reports that consistently show a finding that the Medicare program overpays for the drugs and biologicals it covers. This is because most drugs can be obtained at a much lower cost than the AWP....The OIG's most recent studies are 'Excessive Medicare Payments for Prescription Drugs' (OEI-03-97-00290, December 1997) and 'Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs' (OEI-03-97-293, November 1998). On average, for the 22 drugs in the OIG study, Medicare payment at the AWP allowed a markup of 41 percent above the drugs' wholesale catalog price advertised to the

how in 1997 "the HHS Inspector General found payments based on average wholesale price data to be 11 to 900 percent greater than the prices available to the physician community."[171]

111. The differences between AWP and providers' acquisition costs were also publicized in general circulation newspapers and magazines.[172, 173, 174, 175] Examples of such "spreads" include: doxorubicin, 254 percent;[176] and etoposide, 318 percent.[177] Dr. Hartman's assumption that payors were unaware of the size of "spreads" was explicitly contradicted by a group of approximately 32 health plans (representing 45 million covered lives) who participated in a survey by MedPAC, on which Plaintiffs' rely:[178] "Plan respondents were aware that physicians typically purchased drugs at prices well below AWP and that the payment methods resulted in additional profits for physicians," "some plans used varying percentages of AWP for different categories of drugs," and "[a]bout one-half of the plans considering

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physicians and suppliers who bill Medicare"; see Shalala Report to Congress, 1999, at HHC902-0802–03.

[171] Shalala Letter to Bliley, 2000, at HHC001-0360.

[172] See, for example, Sanger, Elizabeth, "No Rx for Plans; Drug Plans Draw Pharmacists' Ire," *Newsday*, February 24, 1989, p. 47: "insurers say the average wholesale price isn't the price they pay for drugs. Depending on the medicine, the acquisition price can be as much as 50 percent less than the average wholesale price, [Richard] Kaplan [President of the eastern division of CIGNA Health Plans] says. Moreover, there can be several average prices."

[173] "Pharmacists Face Big Losses Under Proposal, Official Says," *Arkansas Democrat-Gazette* (Little Rock, AR), March 23, 1989: "Bill Mc Cutcheon of Dallas, deputy regional administrator of the Health Care Finance Administration, said numerous studies and 'open admission by the people who publish those prices' has shown that the average wholesale price 'doesn't represent the actual cost' to pharmacies 'by any stretch of the imagination.'"

[174] Colburn, Don, "Drug Prices: What's Up?," *Washington Post*, December 15, 1992, p. Z8: citing "deep discounts that large-volume buyers such as chain stores, hospital groups and HMOs can bargain for."

[175] Hooked on Drugs, 1996, p. 15: "For many drugs, especially the growing number coming off patent and going generic, the drug providers actually pay wholesale prices that are 60%–90% below the so-called average wholesale price, or AWP, used in reimbursement claims." These discounts off AWP correspond to spreads of 150 percent to 900 percent. The article lists examples of injectables and IV solutions, some of which are Subject Drugs in this litigation.

[176] Hooked on Drugs, 1996. "Spreads" are calculated as ("'95 AWP" – "Wholesale Price") / "Wholesale Price."

[177] Hooked on Drugs, 1996.

[178] See, for example, Hartman Liability Report, ¶¶ 22 (c), 27.

changing their payment methods for drugs noted that they might have to raise physician administration fees to partially offset the reduced income generated for physicians."[179]

112. According to Professor Berndt: "[K]nowledgeable observers understood that physicians were able to purchase many of the Medicare Part B outpatient drugs at acquisition costs considerably less than AWP,"[180] and the difference between AWP and ASPs has long been highly visible to active industry participants.[181]

B. Payors could (and did) acquire more information

1. Payors could (and did) become involved in drug purchasing

113. Dr. Hartman assumes the only publicly available "signal" of acquisition costs was AWP[182] (without considering TPPs' involvement in drug purchasing[183]), and concludes that "TPPs must have and did look to signals for the costs."[184] However, payors could gain information on drug acquisition costs and spreads by becoming involved in drug purchasing, and some have done so. For example, private payors have acquired specialty pharmacy operations, mail order pharmacy services, or pharmacies and clinics typically through staff model HMOs,[185] or PBMs;[186] these

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[179] 2003 MedPAC Report, pp. 166–167.

[180] Berndt Report, ¶ 97.

[181] In a section discussing reports and investigations by the OIG, VA, HCFA/CMS, GAO, CBO, DHHS, Professor Berndt notes: "While it is not entirely clear why it has taken so very long for CMS to switch from AWP-based to an actual selling price (ASP)-based reimbursement, what is clear is that through these published reports and inter-agency public information exchanges, the fact that pharmacies' and providers' acquisition costs were typically less than AWP has long been made very visible and public. It has not been a secret, at least to active observers and health care industry participants" (Berndt Report, ¶ 65); see, also, Berndt Report, ¶ 74.

[182] Hartman Declaration of Dec. 16, 2004, ¶ 3 (e).

[183] Hartman Deposition, pp. 1013–1015 (Dr. Hartman did not study payors' precise affiliations with staff model HMOs or hospitals, although he acknowledges that a third-party payor should be informed by its subsidiaries that purchase drugs).

[184] Hartman Liability Report, ¶ 35.

[185] For example, Anthem had a mail-order pharmacy service called Anthem Prescription Management; see Deposition of Timothy Hopkins (Executive Director of retail, mail order, and specialty pharmacy operations, Anthem), November 30, 2004 ("Hopkins Deposition"), pp. 16, 38, 45–50, 92–93. See, also, the discussion of Anthem's specialty pharmacy services in "Specialty Pharmacy Market Offers Expansion Opportunity for PBMs," *Drug Cost Management Report*, September 12, 2003. CIGNA used